

**REMARKS**

Upon entry of the amendments, claims 1, 14-16, 19-21, and 27-48 are pending in the above-identified application. Claims 14, 19, 27, 30, 38, 40, 44 and 47 have been amended to such that the recited indicia is more clearly recited as a structural element of the respective claim. Claims 1 and 37 have been allowed.

Applicants gratefully acknowledge the telephone conversation between the Examiner and Applicants representative on 5/9/2007, during which certain differences between the claimed invention and the cited references (further included in the remarks as set forth below) were discussed. No specific agreement was reached.

**Election/Restriction**

Applicant's gratefully acknowledge the withdrawal of the Election requirement set forth in the Office action mailed October 4, 2006, as well as the finality of that Office action.

**Rejections Under 35 U.S.C. §112**

Claims 45 and 46 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

First, Applicants initially point out that the finality of the current rejection is premature and inappropriate because the Examiner has made a new ground of rejection, which was not necessitated by a previous amendment by the Applicant and Applicant has not previously been afforded an opportunity to address this new rejection. As is known by the Examiner, Final rejection on a second or subsequent action on the merits is improper where the Examiner introduces a new ground of rejection that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) (see, e.g., MPEP § 707.07(a)). Here, no amendment to claims 45 and/or 46 was offered in Applicants previously filed response mailed 1/4/2007. As such, withdrawal of the finality of the rejection is respectfully requested.

Second, regardless of the premature final rejection, Applicants respectfully traverse the rejection and submit that one skilled in the art, viewing the specification as filed, would clearly know how to make and/or use the currently claimed invention. The Examiner alleges that the present application lacks an enabling disclosure for a dissolvable dye that dissolves in water or air because no specific examples of such dyes are listed in the application. However, the presence/absence of specific working examples is merely one factor among numerous factors to be considered in determining whether a disclosure satisfies the enablement requirement (see, e.g., MPEP § 2164.01(a)). As set forth in MPEP § 2164.02, "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed."

In the present case, Applicants respectfully submit that the skilled artisan would recognize that many known/commercially available dissolvable dyes are available for use according to the present invention, and Applicants are not required to specifically list every dissolvable dye known in the art. Choosing a dye from among the known or commercially available dissolvable dyes would require any undue experimentation.

Accordingly, for the reasons set forth above, Applicants respectfully request that the rejections of claims 45 and 46 under 35 U.S.C. §112, first paragraph be withdrawn, or if the rejections are not withdrawn, that the Examiner provide some objective indicia or reasoning to support the allegation that undue experimentation would be required in the present instance.

Claim 47 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

First, Applicants submit that final rejection in the present instance is premature and inappropriate, for a similar rationale as set forth above regarding claims 45 and 46. As such, withdrawal of the finality of the present rejection is respectfully requested.

Regarding the basis of the rejection, it is alleged that the original disclosure contains no teaching of using a "peel-away" removable wrapper. Applicants respectfully disagree. The Examiner's attention is drawn, for example, to Figure 7C and the accompanying

disclosure at page 9, lines 13-18 of the originally filed specification, where a "peel-away wrapper 62" is specifically described. As such, written description support has been provided in the originally filed specification.

Accordingly, for the reasons set forth above, Applicants respectfully request that the rejection of claim 47 under 35 U.S.C. §112, first paragraph be withdrawn.

Rejections Under 35 U.S.C. §103

Claims 14-16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent no. 5,975,893) in view of Braverman (U.S. Patent no. 3,780,856).

*Prima facie* obviousness has not been established at least for the reason that the cited references, alone or in combination, fail to teach each and every element of the claimed invention. MPEP §§2141-2143. Neither Chishti nor Braverman, alone or in combination, teach "non-numerical indicia on a package at an end of the chain, the non-numerical indicia comprising information indicating a dental appliance to be worn first" as recited in claim 14. The cited references simply do not teach each and every element of the claimed invention, including claimed structural elements.

Chishti teaches a system for repositioning teeth including a plurality of individual appliances. While Chishti teaches numerical indicia indicating order of use, Chishti does not teach non-numerical indicia on a package at an end of the chain, the indicia comprising information indicating a dental appliance to be worn first, as recited in claim 14.

Braverman teaches in Figure 1, which has been cited by the Examiner, individual units detachably connected together along lines. Individual units are shown having numbers or a combination of a number and the term "after meal". The Examiner has cited the term "after meal" as teaching the claim element relating to non-numerical indicia of order of use. However, Braverman fails to provide the teaching missing from Chishti, as the term "after meal" does not include information indicating a dental appliance (or which individual unit of Braverman) to be worn/used first. If anything, only the numerical indicia on the units of Braverman (i.e., 1, 2, 3, 4, 5) might indicate order of use. Thus, Braverman would not teach any indicia comprising

information of order of use that are not already taught by Chishti. Even if Chishti and Braverman were combined (even though there is no reason to do so), the combination would still not teach each and every element of claim 14 or "all the claimed structure", as alleged by the Examiner. The claim element of non-numerical indicia on a package at an end of the chain, the indicia comprising information indicating a dental appliance to be worn first is a structural element of claim 14, and this structural element is not taught in the cited references, either alone or in combination.

Moreover, the present instance is not merely a matter of employing the same structure of Braverman for a different use (e.g., different mental interpretation and/or intended use). The Braverman "after meal" structure does not teach the non-numerical indicia that would include the information specifically required by the indicia element recited in the claim and, as such, not only does Braverman fail to teach the identified structural element of claim 14 (which alone supports withdrawal of the claim), but the structure taught by Braverman (e.g., "after meal") would not include the requisite information and, therefore, would not be suitable as a non-numerical indicia of order of use even if such "intended use" were attempted.

In the present case, for the reasons set forth above, the Examiner has not established a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the rejections of claims 14-16 under 35 U.S.C. §103(a) be withdrawn.

Claims 19-21 and 48 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Klein (U.S. Patent no. 4,038,753).

The cited references, alone or in combination, fail to teach each and every element of the claimed invention, precluding *prima facie* obviousness. In particular, Applicants respectfully disagree with the allegation that the cited references teach "all the claimed structure" and that the specific meaning of the indicia is merely a matter of mental interpretation/intended use. Neither of the cited references, alone or in combination, teach a non-numerical indicia comprising information designating an order in which each of the plurality of dental appliances are to be worn by a patient to provide dental treatment, as recited in claim 19, for example.

Klein fails to teach non-numerical indicia having information designating order of use. First, the term "A-1-REG" cited by the Examiner is a combination of numbers and letters on the central ring of the Klein article, and appears indicative of central ring size and simply does not teach order of use. Second, nothing on the Klein article includes information indicating which of attached intraoral tension rings are to be used before any others. In fact, since all the rings appear identical, order of use would seem irrelevant in the teachings of Klein. Third, as nothing in Klein includes information regarding order of use, the present instance is not merely a matter of employing the same structure of Klein for a different use (e.g., different mental interpretation and/or intended use). In other words, despite the fact that the structure of Klein (e.g., "A-1-REG") is different from the structure required by the claim (which alone supports withdrawal of the rejection), the Klein "A-1-REG" structure would actually appear incapable of being used as non-numerical indicia designating an order of use. As such, finding each and every element of the claimed invention in the cited references is not merely a matter of mental interpretation and/or intended use, as alleged by the Examiner, but is actually quite implausible.

Accordingly, for the reasons set forth above, Applicants respectfully request that the rejections of claims 19-21 and 48 under 35 U.S.C. §103(a) be withdrawn.

Claims 27-29 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Klatt (U.S. Pub. No. 2003/0136698).

The cited references, alone or in combination, fail to teach each and every element of the claimed invention, precluding *prima facie* obviousness. For example, Klatt fails to teach a package including a plurality of geometrically distinct dental appliances positioned in an arrangement within the package, the positioning comprising information which indicates an order of usage, as recited in current claim 27.

Klatt teaches a stack of blister cards in a package with numerical indication of the number of days left in a drug treatment regime. The stacking of Klatt is taught for the purpose of visualizing length of treatment and drug regime duration, with no indicia or information indicating order of use. In fact, Klatt teaches stacking identical blister cards, rather than stacking

distinct items in any particular order, thereby indicating that order of use is irrelevant in the system of Klatt - just the opposite of the claimed invention. Thus, Klatt fails to teach geometrically distinct articles/appliances positioned in an arrangement within the package, the positioning having information which indicates an order of usage.

The Examiner disregards the fact that Klatt teaches stacking identical blister cards based on the allegation that the term "geometrically distinct" is not defined by the present disclosure, and points out that the blister cards of Klatt are geometrically located in different locations. Applicants respectfully submit that this line of reasoning is without merit. The skilled artisan would clearly understand from the plain meaning of the term as well as the teachings in the present specification that "geometrically distinct appliances" include appliances that are distinct or different with respect to their geometric shape, rather than their relative positioning (i.e., location). Applicants further point out that positioning of the appliances relative to each other is addressed separately in the claim, further underscoring the clarity of the term "geometrically distinct appliances". Thus, Klatt clearly fails to teach geometrically distinct articles/appliances positioned in an arrangement within the package which indicates an order of usage.

Accordingly, for the reasons set forth above, Applicants respectfully request that the rejections of claims 27-29 under 35 U.S.C. §103(a) be withdrawn.

Claim 30 is rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Baggett (U.S. Patent No. 4,811,845).

The cited references, alone or in combination, fail to teach each and every element of the claimed invention, precluding *prima facie* obviousness. The references, for example, fail to teach a plurality of packages wherein each package includes a label having a non-numeric indicia comprising information indicating the order of usage of the corresponding dental appliance, as recited in claim 30.

Baggett teaches use of a combination of numeric and non-numeric indicia (e.g., time, date, day of the week, etc.) for ensuring that a patient receives accurate dose of required

medication at scheduled times. Baggett, however, does not teach non-numeric indicia (e.g., day of the week) that alone includes information conveying order of use. Merely stating a day of the week, without more, does not indicate which day treatment begins or an order of use for a treatment regime greater than 7 days. As such, the references fail to teach each package of a plurality including a label having a non-numeric indicia comprising information indicating the order of usage of the corresponding dental appliance, and wherein a package includes a non-numeric indicia comprising information identifying a first dental appliance in the order of usage, as recited in claim 30.

Accordingly, Applicants respectfully request that the rejection of claims 30 under 35 U.S.C. § 103(a) be withdrawn.

Claims 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Seidl (DE 3925088).

The cited references fail to teach each and every element of the claimed invention. In particular, the references, alone or in combination, fail to teach a label that includes a series of numbers and the non-numeric indicia comprises a marking on one of the numbers, wherein the marking indicates order of usage of the corresponding dental appliance, as recited in claim 31.

Seidl teaches marking on numbers (e.g., price labels with strike-through marks) designed to communicate information about price reduction, but fails to teach marking on numbers where the marking comprises any information indicating order of usage, as recited in claim 31. Thus, not only do the teachings of Seidl fail to teach structural elements required by the claims, but the markings taught in Seidl would be incapable of communicating the information specified in claim 31 - i.e., order of usage. Seidl fails to provide the teachings that are missing from Chishti.

Accordingly, withdrawal of the rejections of claims 30 and 31 under 35 U.S.C. §103(a) is respectfully requested.

Claims 30, 32, and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent no. 5,975,893) in view of Fuller.

The cited references fail to teach each and every element of the claimed invention. In particular, the references, alone or in combination, fail to teach a label that includes a series of numbers and the non-numeric indicia comprises a removal of one of the numbers, wherein the removal indicates order of usage of the corresponding dental appliance, as recited in claims 30, 32, and 33.

Fuller teaches removal of numbers from a record sheet and receipt embodying items entered thereon in connection with the stay of a guest at a hotel. The removal taught in Fuller, however, does not indicate any order of usage of anything, nor does the removal taught by Fuller does not communicate the information required by the claims. The cited references fail to teach number removal, where removal indicates order of usage of the corresponding dental appliance, as recited in claim 32.

Accordingly, Applicants respectfully request that the rejection of claims 30, 32, and 33 under 35 U.S.C. § 103(a) be withdrawn.

Claims 30 and 34-36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Morrish *et al.* (U.S. Patent No. 4,726,970).

The cited references fail to teach each and every element of the claimed invention. In particular, the references, alone or in combination, fail to teach non-numeric indicia comprising information indicating order of use, e.g., comprising a shape, that indicates order of usage of the corresponding dental appliance, as recited in claim 30 and 34-36.

Morrish teaches a package including a bar code printing 35 in Figure 4, but Morrish does not teach a bar code or any shape having information that indicates or otherwise communicates information regarding an order of usage. Simply teaching a shape communicating any information is insufficient to establish *prima facie* obviousness, since the shape/bar code taught by Morrish is not structurally configured to include the information required by the claims

and, therefore, fails to teach the structural element of claim 30 and 34-36 missing from Chishti. Thus, the cited references fail to teach a non-numerical indicia that indicates order of usage of the corresponding dental appliance, as recited in claims 30, and 34-36.

Accordingly, Applicants respectfully request that the rejection of claims 30 and 34-36 under 35 U.S.C. § 103(a) be withdrawn.

Claims 38 and 39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Rohlcke *et al.* (U.S. Patent No. 5,326,259).

The cited references fail to teach each and every element of the claimed invention. In particular, the references, alone or in combination, fail to teach non-numeric indicia comprising information designating an order of use, e.g., non-numeric indicia comprising one or more cutouts so that each polymeric shell has a different cutout pattern, as recited in claim 38.

Wong does not teach color or any non-numeric indicia comprising information indicating order of use. Wong teaches orthodontic reamers with colored handles, where the different colored handles are designed to allow the practitioner to more easily distinguish the differently sized endodontic reamers and avoid confusion between different sized reamers that may be otherwise difficult to distinguish upon visual inspection. No specific order of use of the tools is prescribed by the color designations, instead a particular reamer size selected for use on a patient is determined by the practitioner based on clinical factors.

Rohlcke teaches marking metal orthodontic brackets to identify their orientation (e.g., top side, bottom side) when attached to individual teeth. While Rohlcke teaches that the markings may be colored (e.g., to aid visualization) there is no marking or indicia taught as to order of use and no logical connection between the teachings of Rohlcke (e.g., markings for bracket orientation) and Wong (e.g., color to indicate reamer size). Thus, neither reference teaches color or any non-numeric indicia whatsoever including information indicating order of use of anything. As such, the cited references fail to teach non-numeric indicia comprising one or more cutouts so that each polymeric shell has a different cutout pattern, as recited in claim 38.

Accordingly, Applicants respectfully request that the rejection of claims 38 and 39 under 35 U.S.C. § 103(a) be withdrawn.

Claims 40 and 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Martin (U.S. Patent No. 6,884,071).

The cited references fail to teach each and every element of the claimed invention. In particular, the references, alone or in combination, fail to teach non-numeric indicia comprising information designating order of use, where the non-numeric indicia comprises a computer readable element, as recited in claim 40.

As indicated above, Wong fails to teach color or any non-numeric indicia having information indicating order of use. Martin teaches using electronically legible codings (bar codes) as containing information about the mixing time, the material, the manufacturer and/or the expiration date (see, Marin at col. 7, lines 28-29). Martin fails to teach non-numeric indicia having a structure including information regarding order of use. Neither Wong nor Martin teaches non-numeric indicia having the structure defined by the claims - i.e., non-numeric indicia designating order of use. As such, the cited references fail to teach each and every element of the claimed invention, thereby precluding *prima facie* obviousness.

Accordingly, Applicants respectfully request that the rejection of claims 40 and 41 under 35 U.S.C. § 103(a) be withdrawn.

Claims 42 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Martin (U.S. Patent No. 6,884,071).

The combination of Chishti, Wong, and Martin as applied to claim 40 is overcome for at least the reasons set forth above. While Morris teaches radio frequency identification tags, Morris fails to teach using such tags, or any other indicia, structurally defined to include information indicating order of use. As such, Morris fails to provide the teachings that

are missing from Chishti, Wong, and Martin and, therefore, the cited references, either alone or in combination, fail to teach each and every element of the claimed invention.

Accordingly, Applicants respectfully request that the rejection of claims 42 and 43 under 35 U.S.C. § 103(a) be withdrawn.

Claims 44 and 47 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695).

The combination of Chishti and Wong is overcome for at least a similar rationale as set forth above. Neither of the references, alone or in combination, teach a color indicia comprising information designating an order in which each of the plurality are to be worn by a patient, as recited in claims 44 or 47.

As set forth above, Wong teaches orthodontic reamers having different colored handles. The different colored handles correspond to different sized reamers, but the colors do not necessarily contain information regarding order of use. As the handle color scheme of Wong does not include information regarding order of use, Wong fails to teach the structural element of claims 44 and 47 - i.e., a color indicia comprising information designating an order in which each of the plurality are to be worn by a patient.

Accordingly, Applicants respectfully request that the rejection of claims 44 and 47 under 35 U.S.C. § 103(a) be withdrawn.

Claims 45 and 46 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) as applied to claim 44 above, and further in view of Bates *et al.* (U.S. Patent No. 5,411,295).

The combination of Chishti and Wong as applied to claim 44 is overcome for at least the reasons set forth above. Bates teaches a water dissolvable ink as a tamper-evident label, but Bates does not teach a water dissolvable ink structurally defined so as to indicate order of use of anything. As such, Bates fails to provide the teachings that are missing from Chishti and Wong, and the cited references fail to teach each and every element of the invention, including a

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color indicia comprising information designating an order in which each of the plurality are to be worn by a patient, as recited in claims 44 or 47.

Accordingly, Applicants respectfully request that the rejection of claims 45 and 46 under 35 U.S.C. § 103(a) be withdrawn.

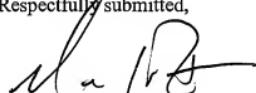
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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